

MODIFIED PTO/SB/08 (08-00)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B-PTO  
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: July 19, 2004

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/734,638
Filing Date	12/15/2003
First Named Inventor	Philippe ROUANET et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	029488-0113

Sheet 1 of 1

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
AME	A1	4,973,755		Heumann Pharma GmbH & Co.	11/27/1990	
AME	A2	4,919,937		Pierre MAUVAIS-JARVIS et al.	4/24/1990	
AME	A3	5,904,930		Hexal AG	5/18/1999	
AME	A4	5,945,109		s.w. Patentverwertungs Ges.m.b.H.	8/31/1999	

**FOREIGN PATENT DOCUMENTS**

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AME	A5	International Search Report	
AME	A6	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Administration to Human Breast", Cancer Research, Vol. 46, 3/1986, pp. 1521-1525.	
AME	A7	F. KUTTENN et al., "Principe de l'administration percutanée des antiestrogènes en pathologie mammaire", Contracept. Fertil. Sex. 1991, Vol. 19, No. 2, pp. 165-171.	
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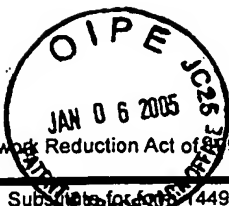
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Subs. (1) for 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: January 6, 2005

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/734,638
Filing Date	12/15/2003
First Named Inventor	Philippe ROUANET et al.
Group Art Unit	Unassigned
Examiner Name	1615
Attorney Docket Number	029488-0113

Sheet 1 of 3

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Amc	B2	J. BARRAT et al., "Effet <i>in vivo</i> de l'administration locale de progestérone sur l'activité mitotique des galactophores humains", J. Gynecol. Obstet. Biol. Reprod. 19: 269-274 1990.	
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Amc	B6	Eric C. DIETZE et al., "Tamoxifen but Not 4-Hydroxytamoxifen Initiates Apoptosis in p53(-) Normal Human Mammary Epithelial Cells by Inducing Mitochondrial Depolarization", The Journal of Biological Chemistry Vol. 276, No. 7, Issue of February 16, 2001, pp. 5384-5394.	
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Amc	B8	I.S. FENTIMAN et al., "Studies of tamoxifen in women with mastalgia", The British Journal of Clinical Practice, Supplement 68, Vol. 43, No. 11, November 1989, pp. 34-36.	
Amc	B9	N. GIAMBIAGI et al., "IMMUNOLOGICAL DIFFERENCES BETWEEN THE ESTRADIOL-, TAMXIFEN- AND 4-HYDROXY-TAMOXIFEN-ESTROGEN RECEPTOR COMPLEXES DETECTED BY TWO MONOCLONAL ANTIBODIES", J. Steroid Biochem. Vol. 30, No. 1-6, pp. 213-217, 1988.	

Examiner  
Signature

*Michael L. Carter*

Date  
Considered

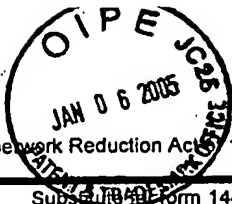
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Subsidiary Form 1449B/PTO		<b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: January 6, 2005  (use as many sheets as necessary)		Application Number	10/734,638		
		Filing Date	12/15/2003		
		First Named Inventor	Philippe ROUANET et al.		
		Group Art Unit	Unassigned		
		Examiner Name	1615		
Sheet	2	of	3	Attorney Docket Number	029488-0113

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AMC	B10	V. Craig JORDAN et al., "Metabolites of tamoxifen in animals and man: identification, pharmacology, and significance", Breast Cancer Research and Treatment, 2, pp. 123-138.	
AMC	B11	George G.J.M. KUIPER et al., "Comparison of the Ligand Binding Specificity and Transcript Tissue Distribution of Estrogen Receptors $\alpha$ and $\beta$ ", Endocrinology, Vol. 138, No. 3, 1997, pp. 863-870.	
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AMC	B19	"First results from the International Breast Cancer Intervention Study (IBIS-I): a randomized prevention trial", The Lancet, Vol. 360, September 14, 2002, pp. 817-824.	
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Examiner Signature		Date Considered	4/21/2004
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Date Submitted: January 6, 2005		Filing Date	12/15/2003
(use as many sheets as necessary)		First Named Inventor	Philippe ROUANET et al.
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		Examiner Name	1615
Sheet	3	of	3
		Attorney Docket Number	029488-0113

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AM	B24	Ian S. FENTIMAN, "Tamoxifen and Mastalgia An Emerging Indication", Drugs 32 477-480 (1986), pp. 477-480.	
AM	B25	Johannes GERDES et al., "CELL CYCLE ANALYSIS OF A CELL PROLIFERATION-ASSOCIATED HUMAN NUCLEAR ANTIGEN DEFINED BY THE MONOCLONAL ANTIBODY Ki-67 <sup>1</sup> ", The Journal of Immunology, Vol. 133, No. 4, October 1984, pp. 1710-1715.	
AM	B26	J. GIRAULT et al., "Quantitative Measurement of 4-Hydroxy Tamoxifen in Human Plasma and Mammary Tumours by Combined Gas Chromatography/Negative Chemical Ionization Mass Spectrometry", Biological Mass Spectrometry, Vol. 22, (1993) pp. 395-402.	
AM	B27	Trisha GURA, "Cancer Models: Systems for Identifying New Drugs Are Often Faulty", Science, Vol. 278, November 7, 1997, pp. 1041-1042.	
AM	B28	Stanley G. KORENMAN et al., "ESTRADIOL RADIOIMMUNOASSAY WITHOUT CHROMATOGRAPHY: PROCEDURE, VALIDATION AND NORMAL VALUES", J. Clin. Endocrinol. Metab. 38:718-720 (1974).	
AM	B29	Catherine MALET et al., "Effect of 4-hydroxytamoxifen isomers on growth and ultrastructural aspects of normal human breast epithelial (HBE) cells in culture", Journal of Steroid Biochemistry & Molecular Biology 82, (2002) pp. 289-296.	
AM	B30	Catherine S. MURPHY et al., "Structure-Function Relationships of Hydroxylated Metabolites of Tamoxifen that Control the Proliferation of Estrogen-Responsive T47D Breast Cancer Cells In Vitro", Molecular Pharmacology, Vol. 38, No. 5, (1990), pp. 737-743.	
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AM	B32	Y. NOMURA et al., "Effects of antiestrogens and medroxyprogesterone acetate on the clonogenic growth of tamoxifen-sensitive and resistant human breast cancer cells", Japanese Journal of Cancer Chemotherapy, 12(4), pp. 844-850 (1985)	
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Examiner Signature	<i>Officer Cotton</i>	Date Considered	4/21/2006
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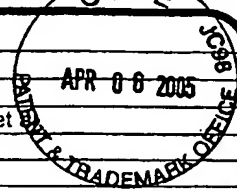
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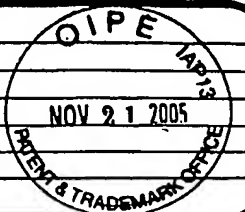
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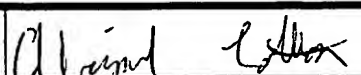
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U.S. PATENT DOCUMENTS						
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AM	E1	BRISSON, J., et al., "Tamoxifen and Mammographic Breast Densities, Cancer Epidemiology, Biomarkers & Prevention, Vol. 9, pp. 911-915 (2000).	
AM	E2	"High Breast Density a Risk Factor", pp. 1-4, <a href="http://www.breastcancer.org/research_genetics_091902_pf.html">http://www.breastcancer.org/research_genetics_091902_pf.html</a> (8/11/05)	
AM	E3	PUJOL, H., et al., "Phase I Study of percutaneous 4-hydroxy-tamoxifen with analyses of 4-hydroxy-tamoxifen concentrations in breast cancer and normal breast tissue", Cancer Chemother Pharmacol, vol. 36, pp. 493-498 (1995).	

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